

REMARKS

A Request for a One (1) Month Extension of Time pursuant to 37 CFR 1.136(a) and (b) is attached hereto.

The above-captioned patent application has been carefully reviewed in light of the final Office Action to which this Amendment is responsive. Claims 1, 6, 9, 12, 13 and 16 have been amended in a further effort to distinctly point out and particularly point out the claimed subject matter. Claim 11 has been canceled. It is believed that no new matter has been added.

Claims 1, 6, 9 and 11-17 currently stand as pending. The Examiner has rejected all pending claims based on previously cited prior art; namely, Hughes, Treptow et al. and Lukacs et al. More specifically, Claims 1, 6, 9, 11 and 13-17 have been rejected under 35 USC 103(a) as being unpatentable over Hughes, Claim 12 has been rejected under 35 USC 103(a) based on the combination of Hughes and Treptow et al. and Claims 1 and 6 have been rejected under 35 USC 103(a) based on the combination of Lukacs et al. and Treptow et al. In addition, Claims 6 and 16, 17 have also been rejected under 35 USC 112, first paragraph, for failing to comply with the written description requirement. Applicant respectfully requests reconsideration based on the amended claims, as well as the following discussion.

Applicant gratefully acknowledges the detailed explanation of the Examiner's overall position concerning the claims of record taken in the outstanding Office Action.

Claims 1, 6, 9, 11 and 13-17 stand rejected under 35 USC 103(a) as being unpatentable over Hughes (US Patent No. 3,449,081).

As previously noted in prior correspondence and in order to successfully maintain a "*prima facie*" obviousness rejection under the Patent Statute, each and every claimed limitation must be found in or be suggested by the cited art, whether singly or in combination. Those limitations not found in or are suggested by the reference(s) must be commonly well known in the field of the invention to one of sufficient (i.e., ordinary) skill at the time thereof. Moreover, one should review the references in their entirety in making such a rejection in which the rejection should not be made based on advance knowledge (i.e., hindsight) of the present invention, especially in making prior art combinations of references. Put another way, there must be a reason somewhere in the prior art to make a purported combination.

The Examiner has opined that Hughes contains each and every claimed limitation of each of Claims 1 and 6 wherein a number of Applicant's recitations relate merely to those of intended use and therefore should carry no patentable weight in terms of the analysis.

Looking at the cited art, Hughes relates to a test kit that further includes a large plastic squeeze bottle 12 retaining a quantity of a color producing reagent 13, see col. 4, lines 19-33. The bottle includes a cap 40 having a strip 41 that permits a major portion of the cap to remain attached while a separated/tethered portion is removed to allow reagent fluid to be dispensed therefrom into a syringe 17. The extending end of the cap includes a series of ring-like sections of varying diameter that are shown in Figs. 4 and 6. The purpose of these sections is not disclosed anywhere in this reference. As to the "read window", the Examiner believes that the cap described by Hughes is plastic and is no different in that sense from that which is presently claimed given that Hughes does not indicate that the cap cannot be transparent and that it is well known to provide plastics as transparent.

Applicant cannot disagree with the Examiner's stated logic regarding the use of plastics. Since the foregoing is true, the Examiner believes that the read window can be disposed anywhere, absent any other limitations. However, it is not believed that the cap of Hughes describes or suggests an optical read window as intended by the present invention. To that end and according to the present invention, a quantity of fluid must be present within the metering tip itself to permit spectrophotometric optical analysis. The read window must permit such detection meaning that: i) the fluid should be contained within the element itself and ii) in a section that permits optical detection without distortion. The first goal is achieved by having the fluid actually retained within the transparent tip and the second goal is achieved by defining a section of the tip that can retain the fluid and also present no significant interruptions of entering and exiting light. The latter is further achieved by defining an axial cylindrical portion that is further defined by a substantially constant and planar (smooth) diameter. Each of the above are clearly shown in each of Figs. 11 and 12, wherein each illustrate a read window whether in the prior art or according to the present invention. A "read window" being defined within a metering tip is not acknowledged herein as being the novel aspect of the present invention.

In Hughes, the cap covers a portion of the bottle 12, as clearly seen in each of Figs. 4 and 6 other than the cap portions that include the ring-like sections. The bottle therefore provides an additional layer of plastic that must be viewed through, wherein the fluid is not actually retained within the cap, but is rather retained in the bottle. Only in the portion of the cap having the ring-like sections is fluid actually retained in the cap. To that end, the cap is not functioning as a metering tip nor is the structure capable of performing the function unless the cap were to be used alone. Second, the cap requires screw threads in order to permit the cap to be attached to the bottle – see Fig. 4 of Hughes wherein screw threads are evident along the entire interior of the peripheral upper portion of the cap. Applicant has herein amended Claims 1 and 6 to more clearly specify the structure of the read window in terms of its interior diameter. Support is found at Fig. 12 for these amended changes. As noted above, Hughes fails to include an axial cylindrical portion that defines a read window according to the present invention.

The Examiner has further stated that fluid is not a recited element in any of the claims and therefore carries no patentable weight. Applicant has now more positively recited the fluid in each of the foregoing claims (Claims 1, 6) along with the read window, such that the recitations are no longer merely “intended use” and therefore should be regarded as part of the claimed invention.

As to each of the method Claims 9 and 13, Applicant does not agree with the Examiner’s simplified characterization of these claims. Motivation for combining references as to manipulative steps for purposes of a method or process cannot be based on the same rationale as that of apparatus claims. Merely providing an explanation that “structure is capable of function” is overly general and insufficient with regard to making an obviousness rejection for purposes of method claims. Additionally, the Examiner has noted that fluid effects would be merely inherent without providing any guidance or direction as to what these effects are and why they would be inherent. None of the prior art references cited by the Examiner refer to or remotely discuss any of the problems/issues being solved by the present methods, so it is unclear as to where such inherency is found.

Nonetheless, Applicant has amended Claim 9 in an effort to clarify the invention. Claim 9 has now been amended to recite a method for performing an optical read of dead volume of fluid in a metering tip. According to the amended method, the tip is attached to a metering apparatus and a volume of fluid is initially aspirated into the metering tip using the metering apparatus. A portion of the fluid volume is dispensed in which at least one stepped area of the interior of the tip is used to latch the fluid being dispensed and reduce oscillations thereof. The remainder of the fluid is then drawn up into the tip and into a read window area of the tip, wherein a upper meniscus of the fluid is flattened by another stepped area disposed between the read window area and the upper tip opening. As such the entire fluid can be adequately tested. Support is found in Fig. 12 and paragraphs [0026] – [0028] of the present application. It is believed that no new matter has been added.

Claim 13 is also believed to be allowable over Hughes in that the fluid is positively recited therein and is manipulated as part of the claimed method. Though Hughes may arguably provide similar structural aspects does not in and of itself create a reason to one of ordinary skill in the prior art to use it for purposes of the presently claimed method. In fact, Applicant takes the Examiner to task in that it appears to Applicant that the ring-like sections used in the cap of Hughes appear to be used for a similar purpose as those in Lukacs et al – that purpose to relate to containers of different size for transferring liquid from the reagent bottle to the syringe. No discussion or evidence of issues or problems of fluid movement are discussed, suggested even remotely. Therefore it would seem to be incredulous for one of ordinary skill, absent hindsight, to have any reason to use the ring-like sections of Hughes for purposes of the herein claimed method. Applicant therefore respectfully requests the Examiner to provide some form of evidence as to motivation or common sense reasoning as to why Hughes would have been consulted for solving Applicant's problem with regard to either Claims 9 or 13. Claims 14-17 are believed allowable for the same reasons.

The Examiner has also rejected Claim 12 under 35 USC 103(a) based on the combination of Hughes and Treptow et al., each of the foregoing references being previously cited by the Examiner. Applicant respectfully traverses this rejection.

As noted above and in order to successfully maintain a "*prima facie*" obviousness rejection under the Statute, each and every claimed limitation must be found in or suggested by the prior art, whether singly or in combination. Those limitations that are neither found in or are suggested by the prior art should be notoriously well known in the field of the invention to one of sufficient skill. To that end, each of the references should be read in their entirety in that there should be a reason provided in the prior art as a whole in order to make the purported combination. Such motivation should not result from impermissible hindsight (advance knowledge) of the invention.

As noted previously, Applicant believes the Examiner has been overly simplistic in his analysis of the method claims of this application at a minimum. Hughes has been discussed infra. As previously noted, Hughes is defined by a screw-on cap. Applicant does not disagree that the cap is made from plastic and that it is known for plastic to be transparent. Fluid is retained within the end of the cap but otherwise fluid is retained within the bottle and not the cap. Also, the interior of the cap is entirely covered by screw threads in the region to which it is attached to the bottle. The Examiner believes it would have been within the reach of one of ordinary skill to have taken the optical windows of Treptow et al. and combined them with Hughes. A combination of Treptow et al. into Hughes, however, would likely destroy the functionality of Hughes' cap, since it would be unable to attach the cap to the bottle, its primary function.

In addition, the Examiner has apparently assumed that the ring-like sections of Hughes are being used for purposes of the claimed method. Applicant disagrees that being capable of performing a function is not the proper rubric for making an obviousness rejection in terms of a method claim. The Examiner has completely ignored the reasons that would be looked to by one of ordinary skill to make the combination. Applicant disagrees in general that a person of ordinary skill being presented with Hughes would have understood that the ring-like sections of the screw-on cap would provide reduction of fluid oscillations. As noted earlier in this paper, it is far more likely that these sections are provided in the cap to account for differences in the size of the syringe and nothing more. The reference is silent on this point, but to find motivation, Applicant believes the Examiner must find additional evidence in the prior art with regard to motivation than what has been provided to date, especially with regard to the method claims.

Absent same, Applicant believes that Claim 9 is allowable over the cited references and therefore Claim 12 is also allowable for the same reasons since this claim depends thereupon. Reconsideration is respectfully requested.

With regard to the combination of Lukacs et al. and Treptow et al. as to Claims 1 and 6, Applicant again believes there is insufficient motivation to make the purported combination. Lukacs et al discloses a fluid dispensing member that includes a series of ring-like sections. The purpose of the ring-like sections is clearly articulated in this reference – that purpose being to accommodate containers of different size into which fluid is being dispensed. See col 2, lines 23-25 of Lukacs et al. Lukacs et al. fails to provide ring sections for purposes of reducing fluid oscillation and the fact that Applicant has determined that an arrangement that looks somewhat similar solves an entirely different and unrelated problem has been used against the Applicant for purposes of this examination. Treptow et al. also fails to discuss or describe these issues. Applicant does not disagree that this secondary reference describes a window for optical testing in general. No discussion is made concerning issues having to do with fluid oscillation or fluid dead volume, as now recited definitively according to Claims 1 and 6, respectively. There is insufficient motivation to combine references to create metering tips as specifically claimed herein. Moreover, structure is missing from both of the cited references with regard to Claim 6 in that Lukacs et al. fails to include a stepped area being disposed above the read window, this read window now being positively recited as having an interior diameter that is substantially constant and planar (smooth) over a cylindrical axial portion. Because neither reference includes this feature, there can be no "*prima facie*" obviousness rejection under the Statute. Reconsideration is respectfully requested.

Finally and as to the Section 112 rejections, the Examiner has rejected each of Claims 6 and 16 and 17 under first paragraph for failing to comply with the written description requirement. Applicant respectfully disagrees with this rejection. The substantially constant and planar interior diameter of the cylindrical axial portion described is most clearly shown pictorially at Fig. 12.

The Examiner has also indicated an issue with the dispensing of a first amount of liquid in which a remaining amount of liquid or fluid remains in the tip. Applicant respectfully refers the Examiner to paragraphs [0026] – [0028] of the specification as well as Fig. 12, in which “dead volume” is drawn back into the confines of the tip. Dead volume is specifically defined by Applicant – see paragraph [0026] as remaining fluid in the tip following dispense. If the Examiner does not agree with the term “aspirate” (even though Applicant believes it is accurate), Applicant is willing to describe the step as “drawn upwardly into” to more closely comport with the specific language of the specification at paragraph [0028] for purposes of Claim 16.

In summary and in view of the above amendment, Applicant believes the above-captioned application is now in a condition for allowance and an expedited Notice of Allowability is earnestly solicited.

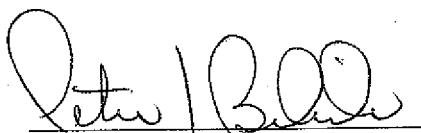
If the Examiner wishes to expedite disposition of the above-captioned patent application, he is invited to contact Applicant’s representative at the telephone number listed below.

The Director is hereby authorized to charge Deposit Account No. 50-3010 for the one (1) month extension fee. It is believed no other fees are required for the filing of this response. However, in the event that any additional fees are required, the Director is hereby authorized to charge Deposit Account No. 50-3010 for any additional fees and to charge any overpayments thereto.

Respectfully submitted,

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